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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1777

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/737,185	<b>Applicant(s)</b> BOWMAN ET AL.	
	<b>Examiner</b> Yelena G. Gakh, Ph.D.	<b>Art Unit</b> 1777	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,38 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21,38 and 40-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. In view of the Appeal Brief filed on 11/29/10, PROSECUTION IS HEREBY REOPENED. The Office action is set forth below. Claims 1-21, 38 and 40-49 are pending in the application.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1777

### **Response to Amendment**

2. The amendment filed 12/15/03 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "the population includes members located at a vessel distribution facility, a specimen collection facility, and a specimen testing facility".

Applicant is required to cancel the new matter in the reply to this Office Action. The recitation of claim 1 completely contradicts the specification, as originally filed, since Figure 4 depicts moving of the specimen containers from one site to another site with no distribution of the "population of biomedical specimen collection vessels" among these sites. No term "population" of biomedical specimen vessels appears in the specification as originally filed.

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### **Double Patenting**

3. Applicant is advised that should claims 1-8 be found allowable, claims 9-17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. A. Claims 1-17, 40-42, 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a diagnostic specimen system comprising a population of biomedical specimen collection vessels, with at least some members of the population located at a vessel distribution facility, a collection facility, a specimen testing laboratory facility. The recitation of the claims contradicts the disclosure as originally filed. Not only the specification does not have the term "population of the vessels" or any of its equivalent, but the only disclosure regarding distributing plurality of vessels is related to Figure 4, according to which the plurality of vessels is moving from one facility to another. No distribution of the plurality of vessels among indicated facilities is disclosed in the specification. On the contrary, according to Figure 4, there are no times, when such distribution among facilities occurs.

B. Claims 1-21, 38 and 40-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "electronic memory tag", which is a broad definition. In

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particular, electronic memory tags are described in US 7,032,822: "[a] memory tag has a non-volatile memory in which in use data is stored, an antenna coil and power supply circuit such that in use the memory tag is powered by inductive coupling. The memory tag also has a sensor for receipt of transmitted light carrying input signals and a processor for processing of the received input signals, and a modulation circuit for overlay of output signals onto the power supply circuit. A read/write device, for communication with the memory tag has a signal generator, an antenna coil and a power supply circuit for powering the memory tag in use by inductive coupling." The specification does not disclose anything similar to the description of the "electronic memory tag" from the patent. Furthermore, the RFID tags disclosed in specification from the various patents are not adjusted for using with the collection vessels. The art related to RFID tags which can be used with collection vessels appears after 2005, e.g. see the article "Calif. Startup Develops RFID-enabled Products to Track Medical Tests ": "Smart Medical Technologies' line of RFID-enabled test tubes, vials and other containers incorporates proprietary 13.56 MHz tags that can store up to 4 kilobytes of data." (Abstract). Also, as the article by Uddin et al. "UHF RFID antenna architectures and applications" (Scientific Research and Essays, 2010), indicates, using RFID tags for vials with liquids require specific adjustment of antenna and RFID field in RFID tags: "[e]arly UHF tags occasionally encountered problems around materials like metal and liquids." Such tags, which have been specifically designed for using in vials were not disclosed in the instant disclosure.

The examiner respectfully reminds the Applicants that according to MPEP §2163:

**"2163.02. Standard for Determining Compliance with Written Description Requirement:**

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental

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factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The Applicants did not show "possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 38 and 40-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Several claims recite "[a] diagnostic specimen system comprising a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members of the population being transported between the facilities". First, the claim language is not supported by the specification, and it is not apparent, how this system is formed. Is this a permanent system, or is this a changing system? Are these vessels constantly located at the indicated facilities? Are the vessels located at recited facilities different from each other? The language renders the claims unclear and indefinite.

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Furthermore, the claims recite that each of the collection vessel includes a wireless electronic memory tag, directly attached to the vessel. First, it is not clear, which specific "electronic memory tag" is meant in the claims, since there are various electronic memory tags, which are designed for different purposes. It is not clear, whether there is a specific electronic memory tag, which is designed to be used for the biological vessels. Further, it is not clear, what it means "directly attached". The electronic memory tag disclosed in the specification is described as comprising a carrier label (4) which has a front face (5) and a rear face (6) with the electronic memory device (9) attached to the rear face. Therefore, it is not apparent what specifically is "directly attached" to the vessel - the label with the electronic memory device? Furthermore, the electronic memory device (9) is described as an ultra-thin radio frequency transponder made up of an integrated circuit and an antenna. However, Uddin et al. in "UHF RFID antenna architectures and applications" demonstrates that developing antenna for the specific purpose is not a trivial task. Therefore, it is not apparent, which specific "electronic memory tag" is recited in the claims, which renders them unclear and indefinite.

The Applicants are respectfully referred to the following excerpt from MPEP:

**"§2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph:**

The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

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The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. Ex parte Ionescu, 222 USPQ 537, 539 Bd. App. 1984)"

Furthermore:

**"§2172 Subject Matter Which Applicants Regard as Their Invention:**

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)."

In the instant case "the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement", and therefore rejection under 35 U.S.C. 112, second paragraph, is appropriate.

In claims 4 and 12 it is not clear, whether the label is the same label that includes the electronic memory device, as disclosed in the specification.

From claims 6-7 and 14-15 it is not apparent, whether the vessel contains a specimen.

From claim 38 it is not clear, where "a tamper-indicating seal" is located on the vessel. This is an essential structural relation omitted from the claim.

Claim 40 is not clear. What does it mean - "an electronic database accessible from the specimen collection facility for storing data entered at the collection facility"? It is accessible for what? The recitation of the claim is not quite clear.

**Claim Rejections - 35 USC § 102/103**

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.



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8. **Claims 1-3, 6-7, 9-11, 14-15, 18-19, 21, 38 and 45-48** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abrams et al. (US 7,070,053) (Abrams).

Abrams teaches "System, method, and apparatuses for maintaining, tracking, transporting and identifying the integrity of a disposable specimen container with a re-usable transponder".

Regarding claims 1-2 and 9-10 Abrams teaches: the RFID tag is attached to a specimen container. "For example, this tag may be secured to any part of the container including the lid, the bottom, the side or the top of the container. As such, the vial may be specifically designed to accommodate the RFID device. Such a tag may include a relatively flat or thin coil connected to an integrated circuit (IC) disposed within the confines of the coil" (col. 8, lines 52-60). "In a further embodiment of the present invention, the vial is designed so that the RFID device is sufficiently secured to the vial so that the RFID device remains attached to the vial during regular shipping and handling." (col. 9, lines 21-24).

Since the vials are specially designed to incorporate the RFID tag, they are manufactured at the "vessel distribution" facility.

The invention is intended for improving the specimen integrity in the chain of custody: "The integrity of the specimen in the vial is becoming increasingly important in the dairy industry and **for drug testing**. It is important to ensure the so-called "guaranteed chain of custody" of the container contents by providing a "tamper-evident" seal to the vial--to protect from being opened by unauthorized personnel who might tamper with the contents" (col. 2, lines 20-26). The chain of custody for drug testing inherently comprises moving the vials with RFID tags from manufacturing facility to collection facility and then to the laboratory facility - the same way as depicted on Figure 4 of the instant application. Since a part of the vials will be located at the same time in these facilities, the plurality of the vials will be distributed among all three facilities.

Regarding claims 3, 6, 7, 11, 14, 15, 18, 19, 21, 45 and 46 Abrams discloses:

"For the drug testing industry, the following is one embodiment of the method of the present invention:

- (a) a disposable vial and RFID tag combination that are assembled as described above;
- (b) information including the date and a unique identification of the vial is written to the RFID device attached to the individual specimen vial;

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- (c) the vials are sent to the office (e.g. physicians office, testing laboratory) where the patients urine or blood specimen is obtained;
- (d) when the patient's blood or urine specimen is obtained, the specimen is put in the specimen vial;
- (e) information including the individual's identification, the time, the day and/or additional office information are written to the RFID device attached to the specimen vial; (f) the vial(s) are sent to a laboratory for analysis;
- (g) at the laboratory, the vials are inventoried by scanning the RFIDs attached to the individual vials;
- (h) at the laboratory, information including the routing (e.g. test required such as the type of drug to be tested for) of the sample is written to the RFID attached to the individual specimen vial; and
- (i) after all testing is complete and the specimen is no longer needed, the RFID device is separated from the vial so that the RFID device may be re-used and the corresponding vial is ground-up so that the plastic may be recycled."

Regarding claim 38, Abrams discloses:

"In yet another aspect of the present invention, the device that secures the RFID device to the vial may be a tamper-proof design for indicating whether the RFID device has been either replaced with another RFID device or has been tampered with during transport to or from a specimen-receiving site and/or during handling. For example, one or more destructible connections may be provided between the RFID device and container, that connection including one or more destructible members which hold the RFID device to the container whereby the RFID device can be removed from the container only in response to the destruction of the destructible member. Accordingly, tampering with the RFID device during transport and/or handling thereof to a specimen-receiving site (e.g. a laboratory) is evident from a destruction of the destructible member." (col. 10, lines 10-24).

### **Claim Rejections - 35 USC § 103**

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. **Claims 4 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams in view of Stevens et al. (EP 1,004,359 A2).

Abrams does not specifically disclose a label imprinted with an identifying barcode, which identifies the vessel.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of

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the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives” (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Abram’s container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to “create a link between the container, the patient and the test request forms”, or any other forms associated with using this container.

11. **Claims 5, 8 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams in view of Stevens, as applied to claims 4 and 12 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

Although Stevens indicated that the label might contain product information, he is silent regarding information on a supplier.

Leuenberger in his “Background of the Invention” related to the blood pack labels indicates, concerning blood plastic containers, “of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc.” (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and because information on a supplier is always conventionally provided with products.

12. **Claims 16, 20, 42, 44 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams in view of Fukuzaki (US 5,948,103).

Abrams does not specifically disclose an encoded electronic signature of a donor of a toxicological specimen stored in the tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

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It would have been obvious for anyone of ordinary skills in the art to employ Fukuzaki's electronic security system, including encoded electronic signature security system, for Abrams' container when it is used for toxicological analysis, because the information contained in Abrams' electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

It is clear from the Abram's disclosure that the RFID tags for vessels at different facilities will have different information according to the function of the facility.

13. **Claim 17 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams, Stevens, Leuenberger and Fukuzaki.

The teachings of Abrams, Stevens, Leuenberger and Fukuzaki are provided above. Abrams discloses specimen vessels with RFID tags distributed between facilities, with RFID comprising the identification code unique for the vessel (or tag), the specimen information, information about the tests to be performed, wherein the RFID tag is a tamper-indicating tag; Stevenes discloses the label with the identifying barcode, Leuenberger teaches the information on the supplier, and Fukuzaki teaches the electronic signature of the patient. The combined teaching of the references covers the subject matter of claim 17, with the motivation for combination of the references provided above.

14. **Claims 40 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams in view of Coli et al. (US 6,018,713) (Coli).

Abrams does not specifically teach electronic database at the specimen collection facility and electronic network for transferring data between specimen collection facility and specimen testing facility.

Coli teaches:

"A network-based system and method for ordering and cumulative results reporting of medical tests includes a computer operated at a physician location (such as a hospital or physician office) to order tests, retrieve and store statistical data or status the progress of previously ordered tests, and at least one labsite computer for receiving physician requests for tests and reporting their results. The physician computer and labsite computer are interconnected by a computer network. The physician computer receives a physician or user request for ordering a test, causes a test request message to be sent to the labsite computer, causes a request for statistical data to be sent to the network, and receives statistical data from the network. The labsite computer is

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programmed to receive a test request message and to cause a test results message or a test status message to be sent to the physician computer" (Abstract).

It would have been obvious for a person of ordinary skill in the art to incorporate Coli's network-based system into the chain of custody system disclosed by Abrams for obvious advantages of using automated paperless management of the specimen and performing tests on them, which allows avoiding human errors.

### **Response to Arguments**

15. Applicant's arguments with respect to claims 1-21, 38 and 40-49 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Y. Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/  
Primary Examiner, Art Unit 1777

1/18/2011